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10/646,296

08/22/2003

Szu-Min Lin

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EXAMINER

CHORBAJI, MONZER R

ART UNIT

PAPER NUMBER

1797

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10/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---------------------------------------|-----------------------------------|--|
| Office Action Summary | Application No. 10/646,296 | Applicant(s) LIN ET AL. | |
| | Examiner MONZER R. CHORBAJI | Art Unit 1797 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/28/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This non-final action is in response to the RCE filed on 8/28/08

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-7 and 9-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cummings (EP 0 373 201 B1) in view of Lin et al (U.S.P.N. 6,589,481).

Regarding claim 1, Cummings discloses a vapor hydrogen peroxide sterilization method for treating medical items (page 2, lines 45-50) that includes the following: placing articles into the container (the ultracentrifuge 10 in figure 1 is considered the container), reducing pressure in the container to a first pressure that is above hydrogen peroxide vapor pressure and below atmospheric pressure (page 4, lines 24-27), introducing a sterilant as a vapor into the container (page 5, lines 35-42), and diffusing the vapor through the container into contact with the articles (page 5, 28-31). As to the limitation of enhancing the diffusion of the vapor throughout the container by reducing the first pressure to a value below atmospheric pressure and above the sterilant vapor pressure, Cummings as explained above apply the vacuum step as claimed and the claimed subject matter is therefore inherent in the Cummings reference as explained in MPEP 2112, II where inherent feature need not be recognized at the time of the invention. However, Cummings fails to teach introducing hydrogen peroxide as a mist.

Lin sterilizes medical devices with hydrogen peroxide generated in a mist form (col.2, lines 63-64), because generating hydrogen peroxide mist is particularly effective in sterilizing articles having inaccessible or hard-to-reach places (col.5, lines 39-41). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the method in Cummings with the hydrogen peroxide in mist form, because it is

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particularly effective in sterilizing articles having inaccessible or hard-to-reach places as explained by Lin (col.5, lines 39-41).

Regarding claim 11, Cummings discloses a method of sterilizing an article (page 2, lines 45-50 where contaminating specimens are considered articles) comprising: placing the article into an enclosure (the ultracentrifuge 10 in figure 1 is considered the enclosure); and reducing pressure in the enclosure to a first pressure (page 5, lines 29-32) then introducing hydrogen peroxide vapor (page 5, lines 36-38) into the sterilization enclosure. As to the limitation of reducing the pressure in the enclosure to a first value to disperse the vapor comprising a sterilant throughout the enclosure and into contact with the article, Cummings as explained above apply the vacuum step as claimed and the claimed subject matter is therefore inherent in the Cummings reference as explained in MPEP 2112, II where inherent feature need not be recognized at the time of the invention. However, Cummings fails to teach introducing hydrogen peroxide as a mist.

Lin sterilizes medical devices with hydrogen peroxide generated in a mist form (col.2, lines 63-64), because generating hydrogen peroxide mist is particularly effective in sterilizing articles having inaccessible or hard-to-reach places (col.5, lines 39-41). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the method in Cummings with the hydrogen peroxide in mist form, because it is particularly effective in sterilizing articles having inaccessible or hard-to-reach places as explained by Lin (col.5, lines 39-41).

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Regarding claims 2 and 14, Cummings discloses generating vapor hydrogen peroxide.

Regarding claims 4-6, Cummings teaches that the first vacuum pressure is at least 5 Torr, or 15 Torr, or 30 Torr below atmospheric (page 4, lines 24-27, the mm Hg unit in Cummings is equivalent to the Torr unit and 1 atmosphere is equal to 760 mm Hg or 760 Torr. For example, 5 mm Hg vacuum is below 5 Torr, or 15 Torr, or 30 Torr below atmospheric pressure).

Regarding claims 16-18, Cummings teaches that the first vacuum pressure is at least 5 Torr, or 15 Torr, or 30 Torr below atmospheric (page 5, lines 28-30, the mm Hg unit in Cummings is equivalent to the Torr unit and 1 atmosphere is equal to 760 mm Hg or 760 Torr where 0.3 mm Hg vacuum is below 5 Torr, or 15 Torr, or 30 Torr below atmospheric pressure).

Regarding claims 7 and 9-10, Cummings teaches the following: sterilizing articles (page 2, lines 45-50), sterilizing the interior of the container (page 5, lines 54-56) and removing residual hydrogen peroxide from the chamber (page 6, lines 5-9).

Regarding claim 3, Cummings discloses generating vapor hydrogen peroxide from a solution of hydrogen peroxide and water (page 4, lines 24-41). However, Cummings fails to teach introducing hydrogen peroxide as a mist. Lin sterilizes medical devices with hydrogen peroxide generated in a mist form (col.2, lines 63-64), because generating hydrogen peroxide mist is particularly effective in sterilizing articles having inaccessible or hard-to-reach places (col.5, lines 39-41). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the method in

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Cummings with the hydrogen peroxide in mist form, because it is particularly effective in sterilizing articles having inaccessible or hard-to-reach places as explained by Lin (col.5, lines 39-41).

Regarding claim 12, Cummings teaches reducing occurs prior (page 5, lines 28-30) to admission of the vapor (page 5, lines 36-38) into the enclosure where the reducing occurs using a vacuum (page 5, lines 28-29). However, Cummings fails to teach introducing hydrogen peroxide as a mist. Lin sterilizes medical devices with hydrogen peroxide generated in a mist form (col.2, lines 63-64), because generating hydrogen peroxide mist is particularly effective in sterilizing articles having inaccessible or hard-to-reach places (col.5, lines 39-41). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the method in Cummings with the hydrogen peroxide in mist form, because it is particularly effective in sterilizing articles having inaccessible or hard-to-reach places as explained by Lin (col.5, lines 39-41).

Regarding claim 13, Cummings teaches that the reducing occurs using a vacuum (page 5, lines 28-29).

Regarding claim 15, Cummings discloses generating vapor hydrogen peroxide from a solution of hydrogen peroxide and water (page 4, lines 24-41). However, Cummings fails to teach introducing hydrogen peroxide as a mist. Lin sterilizes medical devices with hydrogen peroxide generated in a mist form (col.2, lines 63-64), because generating hydrogen peroxide mist is particularly effective in sterilizing articles having inaccessible or hard-to-reach places (col.5, lines 39-41). It would have been obvious to

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one of ordinary skill in the art at the time of the invention to provide the method in Cummings with the hydrogen peroxide in mist form, because it is particularly effective in sterilizing articles having inaccessible or hard-to-reach places as explained by Lin (col.5, lines 39-41).

Regarding claim 19, Cummings teaches that once a vacuum is established (page 5, lines 33-34) vapor is admitted into the enclosure (page 5, lines 36-38). However, Cummings fails to teach introducing hydrogen peroxide as a mist. Lin sterilizes medical devices with hydrogen peroxide generated in a mist form (col.2, lines 63-64), because generating hydrogen peroxide mist is particularly effective in sterilizing articles having inaccessible or hard-to-reach places (col.5, lines 39-41). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the method in Cummings with the hydrogen peroxide in mist form, because it is particularly effective in sterilizing articles having inaccessible or hard-to-reach places as explained by Lin (col.5, lines 39-41).

Regarding claim 20, Cummings teaches that the first pressure is a negative pressure (page 5, line 30).

5. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cummings (EP 0 373 201 B1) Lin et al (U.S.P.N. 6,589,481) as applied to claim 7 and further in view of Jacobs et al (U.S.P.N. 5,785,934).

Cummings tests the efficacy of the vapor hydrogen peroxide sterilization method by inoculating coupons with 10^6 *Bacillus stearothermophilus* (pages 6-7) prior to sterilization. Cummings further teaches sterilization cycles of 4 or 8 or 16 minutes (page

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7). However, Cummings and Lin fail to teach inoculating stainless steel blades with 10^6 *Bacillus stearothermophilus*. Jacobs teaches inoculating stainless steel scalpel blades with *Bacillus stearothermophilus* (col.30, lines 49-53). It would have been obvious to one of ordinary skill in the art at the time of the invention to further provide the modified method in Cummings/Lin with the addition of 10^6 *Bacillus stearothermophilus* inoculated stainless steel blades as taught by Jacobs in order to guarantee the sterility of surgical devices so that no post-surgery infections occur.

Response to Amendment

6. The Declaration under 37 CFR 1.132 filed on 8/28/08 is sufficient to overcome the anticipation rejection of claims 1-7 and 9-20 based upon Cummings (EP 0 373 201 B1).

Response to Arguments

7. Applicant's arguments see pages 6-8, filed on 8/28/08 in combination with the 1.132 Declaration filed on 8/28/08, with respect to the rejection(s) of claim(s) 1-7 and 9-20 under anticipation by Cummings have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of over Lin as shown above.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571)272-1271. The examiner can normally be reached on M-F 9:00-5:30.

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9. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. R. C./

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797